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in the formation of  
small biotechnology firms**

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## **The embeddedness of routines in the formation of small biotechnology firms**

by

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## **Abstract**

There is a continuing focus on the conditions for and processes of establishing new businesses and the role played by the external resource context in doing so. Using sociological concepts such as network bricolage and structuration some studies point to the supporting role as well as the restraining role of networks in this process. However, most research focuses on the innovative role of entrepreneurs in linking together dispersed resources in forming a concerted business enterprise. Far less focus has been on the de facto quality of these resources in forming the entrepreneurial role. Rather, the image of the Knightian or Kriznian entrepreneur is left unchallenged, even in the “new” literature on entrepreneurship. However, if the concept of network bricolage or structuration as contexts institutionalising specific practices and sorting away others is taken seriously, the pre-existence of patterned work practices shared among business actors, and how the ability to utilise these patterned practices in generating new business ideas affects the business start up process becomes important. Entrepreneurial processes may not only be influenced but also internally constituted by the wider environment. One may therefore question whether the impetus for starting up a new business vests entirely with the entrepreneur or what role the context plays in patterning the work of the entrepreneur with respect to firm creation. As pointed out by Gartner (1988) asking “who is the entrepreneur?” is the wrong question. For that purpose, we believe that the context of the entrepreneur, networks and embedded routines, provides an opportunity to understand how the context contributes in shaping the entrepreneurial act.

## **Introduction**

We define firm creation as the initiative and processes leading to the establishment and formalisation of a new business enterprise as a legal entity. Establishing a new firm holds essentially both an element of entrepreneurial initiative and a process of creating acceptance from multiple stakeholders vested in the environment of the entrepreneur, upon which firm creation is depending. From the perspective of institutional sociology the latter process may be seen as one of creating organisational legitimacy within regulatory, cognitive and normative institutional settings. The institutional approach is concerned with the content of the environment in terms of purposes, properties, resources and sovereignty and its role in structuring social actors as well as channelling social actors. For instance, North see’ institutions as constraints for human actions, providing the

order necessary to reduce exchange uncertainty (North, 1990). Such rules are seen as embodied in consensual values, rules and techniques which are highly culture-dependent as they are constituted by human action and through processes of socialisation. We agree with Jack & Anderson (2002), who suggest that social embeddedness is a variable, which is contingent on causes and consequences, which are highly space-specific. Secondly, we believe that services rendered by embedded routines in firm creations primarily serve the purpose of creating legitimacy from the institutional contexts for the business enterprise. Legitimacy can be seen as a commodity through which the organisation gains acceptance and access to resources from the wider environment. In particular for firm creation purposes this commodity is critical, since entrepreneurship usually depends on external resource access.

We study this phenomenon through case studies of business start-ups in the biotech sector in three countries within three regions of the world, which represent very different institutional contexts: Denmark and USA. The biotech sector provides a strong empirical background for investigating entrepreneurship activities since frequent business start-ups (and closures) is a distinctive characteristic of the biotech industry. Each of the cases concerns university scientists, who decide leave the university in order to establish their own company.

Our paper is structured as follows: First we outline the field of biotechnology, which forms the background for our study. We then describe the routine concept as way of storing and retrieving patterned actions by the contexts, which can be used in promoting business start-ups and describe four characteristic problems for biotech start-ups, for which the network embedded routines may provide or enable solutions in the process of creating legitimacy. These problems include: market enactment, attraction of venture capital, relations to public authorities and university relations. We then move on to our case studies, presenting each business start-up case and how the problems outlined here have been solved. In the final part of our paper we analyse the cases and discuss our findings. In our discussion and concluding part, we draw implications for practitioners and academia.

### **Biotechnology - an ‘enabling technology’**

In its present sense biotechnology is a complex technology that consists of multiple technologies, techniques, research areas and professional identities. Many of these technologies and techniques are based on old technologies that have been extended due to the development of new ones. In general, research and development in the area of biotechnology depend on advances in other

technological fields. First of all it depends on information technology, e.g. the development of simulations of molecules and secondly it depends on developments in the area of new materials for example to build fermentors and medical devices with improved performances. The development of biotechnologies therefore requires skills and competencies in multiple techniques and processes in order to manage the process of taking a product from the scientific and experimental stage to production. Therefore, biotechnology can more appropriately be described as an “enabling technology” because it combines new materials and information technology in ways that facilitate new products that could not be produced by applying any of the elements isolated. (Oakey et al., 1990). One example would be the development of biotechnological process plants that requires combining skills in biotechnological processes with advanced computer measurements and the construction of stainless steel tanks (Norus, 1998).

The implications of labelling biotechnology as an enabling technology are that biotechnology is defined as a series of related cross disciplinary concepts rather than trying to break each of the underlying techniques into a single technology e.g. genetic engineering. Instead of building up concepts grouped round types of products or industrial segments for instance foodstuffs or pharmaceutical products the idea is to acknowledge the variety of industrial applications that the advantages in modern biology have opened for. Despite our strong attention to the pharmaceutical industry it is important to stress that the new biotechnologies are applied in the development also in the chemical industry, the agro industry (both animal production and plant production), the food industry, the energy industry and the environmental industry. The new biotechnologies are almost tailor-made for the pharmaceutical industry. The new biotechniques are to be regarded as additional tools that lead to competition with the established skills and competencies represented by the existing process techniques. Traditionally, the pharmaceutical industry has relied on chemical synthesis and thereby the skills of pharmacists and chemists. Irrespective of this orientation, the pharmaceutical industry has been the industrial sector that has attracted the greatest interest in relation to development and investment in new biotechnology products and processes. About 70% of all investments in biotechnology, both private and public, tend to be allocated to the pharmaceutical area. In the pharmaceutical industry the application of biotechnology traditionally has been to develop four groups of products: 1) Diagnostic products, products that can detect diseases and infections, such as AIDS, hepatitis, and blood lead poison, pregnancy, etc. These types of products are normally test kits or diagnostic devices. 2) Therapeutics, which is products used in medical treatment to alleviate and cure diseases and

products that seek to cure and prevent diseases, such as vaccines. 3) Medical devices. 4) Platform technologies, products that aim at improving or replacing existing process technologies in the production of pharmaceuticals.

This means that if biotechnology is applied to Scott and Meyer’s discussion on technical versus institutional environments it is clear that we face an industry that operates in four different sets of domains (Scott & Meyer, 1991). Hence we must expect and take into consideration that the contextual dependencies as well as the organizational routines might be formed and shaped accordingly to the specific technological domain that the small biotechnology firm is seeking to exploit. In table 1 we have turned Scott and Meyers two-by-two matrix into an analytical tool to make it possible to incorporate different types of biotechnology activities that corresponds to their specific institutional/regulatory domains. We have substituted the concept of technical environments at the vertical axis with the aspect of what testing environment the company has to comply with. Do the firm need to test their product candidate on human beings or not. At the horizontal axis we have replaced ‘institutional environments’ with the degree to which the products in question are in a weak or strong regulatory domain. Consequently we have put the four case companies that we deal with according to their typification.

Table 1: Technical and regulatory domains in pharmaceutical biotechnology

	Weaker regulation		Stronger regulation
Non-human testing	<b>Platform technologies</b> (ThermoGen)		<b>Medical devices</b> (Kem-En-Tec)
Human testing	<b>Diagnostics</b> (AndCare)		<b>Therapeutics</b> (Cobento)

## **Four types of institutionalized routines**

An important issue for our research concerns the networked environments' ability to memorize and reproduce activities in support of the legitimacy of a new venture. In other words, how do contexts learn and how do they contain and retrieve this knowledge? The concept of organizational routines as a feature of collective memory provides us with an important key for our understanding of this feature of networked environments (Nelson & Winter, 1982).

A routine may be defined as a patterned sequence of learned behaviour involving multiple actors who are linked by relations of communication and/or authority (Cohen & Bacdayan, 1994). Individual routines combine to become collective responses, which may be further configured, selected or otherwise linked to various other forms of routines. In this form, routines describe the capabilities of organised economic activity (Nelson, 1991).

For individual actors, the system of routines in which they can engage signals a pattern of predictability in which actors have invested through their development of skills (Norus, 1999). Each employee handles uncertainty in interpreting the acts of others. The uncertainty involved relates to the cognitive abilities and limitations of human beings. It follows that patterned sequences of learned behaviour, i.e., routines, are formed through social practice and that they are most likely to emerge in connection with the making of some specific output such as a product. Hence, the involvement of new actors in existing routines is highly dependent on coordinated reciprocity (Weick, 1979).

In social interaction, rules and norms emerge which have properties similar to those of routines in terms of producing concerted individual action in order to attain organisational performance. Rules are common-sense constructs or webs of signification shared by a range of individuals who belong to a specific socio-cognitive society such as a profession (Kallinikos, 1989; Koppl & Langlois, 1994). This notion links to embeddedness, which sees patterns of interpersonal coordination as being interlinked in broader social structures and partly governed by the entrenched and ongoing contextualisation of exchange systems which may be noticed in the emergence of norm systems and of regularities in conduct (Granovetter, 1985).

In the following, we will address the role of routines in relation to the creation of legitimacy in the firm creation process. We will focus on processes of firm creation initiatives taken on by

scientists in the biotech sector, where a subset of particularly critical issues in relation to establishing legitimacy in firm creation processes can be raised. Rather than taking an explorative account of which factors may be seen as critical in different institutional contexts, we have selected these factors in order to conduct a comparison across institutional contexts concerning the role of the entrepreneur and that of proposed embedded routines. Very few comparative studies have been made on entrepreneurship. We expect critical issues to take on different meaning in specific institutional contexts, and correspondingly we assume that the nature of the externally evoked routines will differ in correspondence with institutional variation. We have chosen to focus upon market enactment, attraction of venture capital, relation to public authorities and the relation to off-spring university, as four distinct problems of creating legitimacy. In our analysis we seek to address what role the network embedded routines play in solving these issues for the business venture.

#### Market Enactment

Market enactment concerns the creation of the business idea upon which the proposed firm rests. As pointed out by Hayek, knowledge is distributed in its form, which makes it possible for entrepreneurs to discover exchange possibilities as resource holders value their resources differently, because of differences in knowledge of use. According to Kirzner (1979), entrepreneurial discovery relates to the interpretive faculty or alertness of the entrepreneur. The entrepreneurial discovery may be more or less deliberate and obvious (Demmert & Klein, 2003), suggesting that the entrepreneurs' ability to conduct entrepreneurial discoveries rests on their access to knowledge. However, as suggested by several, entrepreneurial activities often unfold in teams and wider networks, calling in for various incubators and interface services in maturing their idea (Johannisson, 1988; Clarysse & Moray, 2002). In particular, relating to the process of research-based spin offs, entrepreneurial teams are often seen as levers of business formation (Clarysse & Moray, 2002). We expect that the affiliation with these external providers of knowledge may render some entrepreneurial discoveries as more prone than others. In particular, we assume that market enactment may be partly fuelled by the availability of embedded routines in the network of the entrepreneur and that the efficiency of these routines differs with respect to their ability to meet different legitimacy issues facing the firm creation process.

#### Attraction of Venture Capital

Attraction of venture capital is another important issue, particularly in the biotech business creation processes (Mangematin et al, 2002). Venture capital firms have played an interesting and central role in the biotechnology community. A venture capital firm is in principle a financial institution or a money tank whose mission is to place money in high-risk investment projects or ventures. The term high-risk investment should be taken literally, the basic rule being that only one of eight projects is profitable. Venture capital firms carefully develop their projects in calculated portfolio investments to minimize losses. One way of minimizing losses is to hold a majority of shares in the venture. Normally a venture capital firm holds around 70% of the shares in small biotechnology firms in exchange for providing the capital. Aside from appointing the CEO, the venture capital firm has the power to make decisions about selling the firm, licensing agreements, strategic alliances and outsourcing activities. There are two major reasons for the governance of the venture capital community concerning engagements in the biotechnology industry. First, venture capital firms experienced vast losses in the early phase of the biotechnology industry. Second, the structure of the venture capital community has changed. Institutional investors such as pension funds have weakened the role of the philanthropic venture capital ideal (family and private foundations). Also the structure of the investment has changed. Prior, the biotechnology firm if successful went from venture capital funding to an IPO (initial public offering). Now strategies of the venture capital firms have changed into a venture capital process with several rounds of VC-funding before an IPO. Normally the entrepreneur has no prior relations to the venture capital community, and this is one of the major problems that the small biotechnology entrepreneurs are facing. Also the entrepreneurs often do not have a deep insight in the venture capital process and that creates problems right from the beginning. First problem is how to approach the VC's. Second problem is how much money to ask for. Third problem is that of leaving authority and control of the firm. Fourth problem is sharing the potential profits with the venture capitalists (Norus, 2002).

#### Relation to Public Authorities

Public authorities constitute a vital part of the regulatory institutional context facing processes of firm creation. For business entrepreneurs, public authorities and administrative bodies do not represent a unified group of actors with a common goal. Rather they have diverse purposes and represent conflicting interests, for instance both in terms of promoting innovation (i.e. through tax incentives and formation of institutions supporting business start-ups) as well as demanding

certain policies of the firm (tax laws, laws regarding personnel management, etc) restricting the forms these innovations may take. Not least, in relation to business start-ups in the biotech sector, public authorities and approval boards have a decisive influence on business activities. Laws and regulations in relation to approval procedures, regulations of research activities (for instance in relation to cloning and testing of drugs) are important legitimacy issues facing entrepreneurs in the biotech sector (Norus, 2002). In particular, for entrepreneurs, whose primary competence is in conducting research, the lack of familiarity towards the policies and rules of public authorities can be perceived as an insurmountable barrier (Norus, 1999). Network embedded routines for developing legitimacy toward public authorities are likely to be found, as experienced entrepreneurs, consultants and specialists may “know the ropes” and hold the necessary knowledge for business development. For instance, so-called “business angels”, which may provide entrepreneurs with the necessary experiences or contacts are commonly found (Westhead & Wright, 1998). Regulatory policies co-vary with institutional contexts at both the national and the regional level. Moreover, the demand for externally embedded resources of these matters may also strongly depend on the complexity of these environments. We therefore assume, that the nature and function of externally embedded routines will reflect differences in institutional contexts.

#### University Relations

A common and probably universal characteristic of most biotech start-up firms is that their founders usually have a scientific background and for that reason are members of researcher networks as well as have extensive knowledge and formal affiliations to the university world. For that reason, the biotech entrepreneur is faced with a set of specific legitimacy issues, although we expect their magnitude and characteristics to unfold contingent on the institutional context. In a study of science-based spin-offs from a research university, Steffensen, Rogers and Speakman (1999) identified negotiations of property rights, sharing/use of university facilities, maintaining resource exchange facilities with the university and ensuring the possibility for a return to a tenured position at the university, should the venture project fail. We expect that the process of handling university relations during processes of firm creation differs markedly across institutional contexts for several reasons: first, universities are differently positioned in their regulatory context, and for that reason host different policies with respect to negotiating property rights with spin-offs and to what extent and under which conditions entrepreneurs are allowed to

use and share university facilities during firm creation processes. Moreover, normative institutional contexts, with respect to the university scientists' social position in society and their legitimacy as entrepreneurs are likely to differ. This in turn may impact on their ability to escape the hazards of entrepreneurship and retreat into tenure. Correspondingly, and reflecting these institutional differences on university relations we expect to find markedly different embedded routines constituted in the network of the entrepreneur. Whereas universities in particular contexts provide several complementary routines for handling science-based spin-off issues, we expect them to differ, reflecting the normative context and regulatory context. Hence, university bodies and informal science networks may vary with respect to their support and their ability to facilitate firm creation processes.

### **Presenting the case studies**

In order to tentatively subject our ideas to some empirical data, we take departure in a set of case studies conducted on biotech start-up firms. The empirical findings stem from longitudinal case studies that have taken place since 1991 in the Danish biotechnology firm, Kem-En-Tec. ThermoGen and AndCare has been investigated from 1993 until 2001. Whereas managers from Cobento has been interviewed during 2002. The data has been gathered through series of interviews sessions with the entrepreneurs, members of the management team and key personnel into both the research labs and the business development. The great advantage of longitudinal case study method has been our ability to follow the four firm's development and establishing relationships to the four major actor groups in our paper, the access to new knowledge through university relations, their relations and access to the venture capital community, the firm's interpretation and creation of the market relations and the development of relations to the public and regulatory bodies.

#### *Kem-En-Tec – Medical Devices*

Kem-En-Tec was established as a merger between two small biotechnology firms, JKA Biotech and Kem-En-Tec Partners, both of which were founded in the beginning of the 1980s. Both firms had roots in Danish research institutions: JKA Biotech originated from Denmark's Technical University whereas Kem-En-Tec Partners was established from a laboratory at University of Copenhagen. Kem-En-Tec Partners was founded by two associate professors at the Protein Laboratory together with one of their graduate students. The three founders had developed a

technique that made it possible to produce proteins of a better quality and at a cheaper price. The focus of their business was to develop and produce plant proteins for research and development purposes in both industrial and university laboratories. JKA Biotech had specialized in the development of technical devices and equipment that could be used to characterize and purify of proteins. Unlike the people from Kem-En-Tec Partners, the researchers from Denmark's Technical University already had developed the equipment but they lacked a clear vision or an idea of how to sell and market the device. The solution to the problem of both companies appeared in 1987 when the two firms decided to enter into a partnership by establishing a joint sales company Kem-En-Tec. Series of changes went on after the company successfully were able to attract two venture capital firms to invest in the firm.

Market enactment. In the initial phase of Kem-En-Tec's history, the long-term perspective was to launch products for the established biotechnological industry and the large research institutions. Kem-En-Tec started out selling to the research community and these contacts were established through the scientific community that the founder was familiar with and also a part of. The firm was too small to function as a supplier of products to especially large customers (companies and research institutions). It was difficult to be acknowledged as a reliable partner since this required that the firm could meet customers' requirements. The firms had difficulties in establishing relationships of trust, i.e., could the customers trust the firm's ability to deliver the required products just-in-time and were they capable of fulfilling the technical standards. Also, in the research community, it is difficult to create the necessary trustworthiness. To overcome this, a consultancy service was initiated in order to demonstrate to future customers that the company had the skills and should be recognized as a legitimate partner within the biotechnological community. Doing consultancy made it possible to improve the financial situation and also broadened the technological scope by getting access to work with process technology at a large scale. The consultancy services meant that Kem-En-Tec was acknowledged as having the necessary competencies to develop reliable devices.

Relations to the university. A second form of market contact was established through scientific publication and active participation in related research conferences. This is an indirect way of approaching and creating a market for new biotechnology products and processes that all biotechnology firms in my population of entrepreneurs has experienced. In the case of Kem-En-Tec, the firm built up its profile through scientific publication in journals in the area of process development. These articles were afterwards used as a sort of advertisement; Kem-En-Tec

offered to make some tests that could improve a partnering firm's products and also demonstrate Kem-En-Tec's capability.

Indeed, Kem-En-Tec kept up with a variety of procedures and norms rooted in its academic past. First of all, the company maintained the individual's right to spend time on so-called 'leisure projects' or bootleg projects, allowing the employees to work on projects that had no relation to the formal activities. The bootleg projects served a dual purpose: they were long-term investments given that they proved to have commercial interest.

Access to venture capital. One of the very few Danish venture capital firms, Scantech, showed interests in the firm in 1989. After intense and almost existential discussions between the founding entrepreneurs of the two initial firms, they agreed on going for venture capital money to develop the firm. A few months later another Danish venture capital firm, Danish Development Finance (DDF), invested in the firm. DDF had special interest in one of Kem-en-Tec's development projects and its investment was solely targeted toward this single development project. The project orientation that was enforced by the venture capital firms meant that each project had its own sponsor and its own distinct business model. Eventually, this also forced Kem-En-Tec to separate the two most promising projects into two subsidiary firms.

Relations to regulatory bodies and public institutions. Due to the nature of the organization of the company and the way that they had targeted their products Kem-En-Tec did not have to build up relationships directly with public regulatory authorities. Another reason for this was that Kem-En-Tec also sold off or spun-off projects to industrial partners when the development projects showed clear commercial perspectives. In that sense a combination of the firm's interpretation of the market, the nature of the technologies that they aimed at and the predominant research culture meant that they could stay out of developing these relationships.

### *Cobento Biotech ApS*

Cobento Biotech is a Danish biotech producer of human vitamin B12 binding proteins. Lars Berglund (LB) formed together with five scientists from the University of Aarhus and the University Hospital in Aarhus, Denmark, the company after discovering recombinant human proteins grown on plants that can be used to promote the uptake and utilisation of vitamin B12. The use of plant material for the production of these human vitamin B12 binding proteins is significantly better and less expensive than the current methods such as animal or yeast products.

The company was formed in November 2001, and has recently attracted sufficient venture capital for full-scale production from a group of Danish venture capitalists.

Market enactment. The business start-up of Cobento was based on previous collaboration between LB and colleagues from agricultural biotech research in plant genetics. In the early 90's LB started working in a new DNA laboratory at the University of Aarhus. The lab was the only one with experience in protein chemistry and got funding from the Danish Dairy Industry. The lab attracted several international experts who taught LB and his colleagues how to isolate and characterize proteins as well as producing them using transgenic organisms such as yeast and plants. As the clinical aspects of milk proteins was part of their research focus they came in contact with Ebba Nexø (EN), a professor at the university hospital with an in-depth knowledge of this area: By combining her knowledge about B12 deficiency with his own expertise in isolating the genes and from mapping the genes, LB formulated his business idea. He invited EN to join his company together with several work colleagues from the DNA laboratory and Erik Ø. Jensen (EØJ) with whom he had previous work experience in growing transgenic plants. EN contributed with her network from the clinic in her own hospital, other Danish and international hospitals.

Cobento Biotech was a global company from its initiation. In the business plan LB pointed out the potential customers world wide using intrinsic factors for B12 deficiency treatment and their current customers are all large multinationals. Moreover, parts of their current staff are international and their network contacts are mainly found in the international community of biotech and medical researchers in the US, UK and in Germany.

Relations to the University. According to LB, the university has not actively supported nor hindered the establishment of Cobento Biotech. However, the company is currently located at the Aarhus university science park close to the university campus. This park provides office space, administrative facilities to a relatively low rent for business start-ups affiliated with the university, and has been an important incubator of several biotech companies in Denmark (Norus, 2002). The company experienced few problems with the transfer of ownership rights. When considering the start-up of the firm, the founders filed a note to the University late December 1999 just before the University changed their regulations for ownership of knowledge. The procedure was to notify the university on the invention and thereby giving the founders the total ownership. According to LB the new regime means that the

university will put its hand on the invention and that inventions may be lost due to lack of motivation and funding capital. LB finds it nevertheless important to keep a close relation to the University to maintain access to technical equipment and knowledge. For instance, LB's former boss, who is also in the company, keeps his tenure. Likewise EN stays in the hospital and EØJ still works at the plant laboratory. As a result Cobento still has 3 key persons, who give the company access to a wide range of resources, including lab facilities, potential employees, etc.

Access to venture capital. In terms of raising venture capital the market has become very tight. A few years ago, the biotech sector was regarded as highly attractive for venture capitalists and capital was well available. However, as many ventures have failed, it is much harder today to raise venture capital. At the beginning the founders themselves together with a seed capital investment from the Teknologisk Institut (DTI) financed the establishment of the company as an "ApS" (a limited company). The money from DTI was dedicated to cover the expenses of filing for the patent, lawyers and other people that helped in setting up the company. Again the network of Lars Berglund became useful since one of his previous colleagues worked at the DTI.

Today Cobento, based on their lobbying activities, has reached an agreement with 4 different Venture Capital companies that were found in a screening process of 8 – 10 potential partners. The founders will end up with half of the ownership and explicit restrictions concerning their future position within the company.

Relations to regulatory bodies and public institutions. The experience of handling the administrative experience in Cobento and setting up accounting procedures etc has been strongly supported by the Aarhus science park, and accountants paid for by the seed capital issued by Dansk Teknologisk Institut. An important issue however, concerns gaining permission to grow transgenic plants on free land. Here, Danish public authorities are fairly restrictive, with respect to allowing genetically modified plants into the Danish biosphere. So far, all experiments with transgenic plants have been carried out in specifically sealed green houses. Again, an important source of routine-based knowledge has been provided by the contacts of EØJ who has been able to draw on his personal experiences and that of his networks in handling the Danish farming authorities.

### *ThermoGen Inc. – Platform Technologies*

In 1988 David Demirjian fostered ThermoGen Inc. together with his former professor from the University of Chicago, Malcolm Casadaban. The firm is located in Chicago, Illinois and until 1998 it rented its facilities from the incubator in the Chicago Technology Park.

The platform technology is to develop and utilize thermophilic organisms that are used as biocatalysts. The biocatalysts, which are specific types of enzymes, can be used in industrial processes, for example in the development of foodstuffs, chemical products and pharmaceutical products. In relation to traditional industrial enzymes, thermophilic enzymes are more stable and can function in high temperatures. Hence fermentation processes can be carried through much faster than is the case with existing techniques. ThermoGen did not search for venture capital money to develop the firm.

Market enactment. ThermoGen's opinion in this regard was that the pharmaceutical industry is the most open-minded when it comes to new process technologies because if a pharmaceutical firm does not make use of the latest and most sophisticated technologies it will lose money on its products. This statement is in opposition to the experience of Kem-En-Tec when it introduced its process technologies to the pharmaceutical firms. The different experiences can have to do with the technologies that the two firms have utilized. For instance, ThermoGen has introduced a test kit-alike product that can find the most efficient biocatalysts from a large sample of thermophilic organisms. Such a system helps to optimize the existing ways of fermenting and makes it possible to have both a faster process and cleaner fermentation processes. This makes ThermoGen's processes more applicable compared to a situation where large process plants have to be readjusted. In the agricultural sector and in the food industry the attitude towards new technologies is different. The technologies the food industries rely on are regarded as sufficient and reliable since they have proven successful over the years. These industries are willing to use alternative technologies if the food industries do not have to be active in the development of the technology. It has to be technologies that can replace the old technologies with a minimum of switching costs.

Relations to university. The initial problem was that the University of Chicago had the ownership rights to the research that was carried out in the laboratories. The group therefore contacted the "University Commercialization Centre," an institution financed by the State of Illinois. The aim of the centre is to support the transformation of research projects into entrepreneurial firms. The centre was at that time located in the University of Chicago

Bookstore, coincidentally the very same building as the research department of the group. The present Vice president of ThermoGen, Ray Willis, was at the time the director of the University Commercialization Centre and would ultimately be an important resource person in the process of realizing the dream of turning the group's basic into a growing firm. Willis has an almost endless personal network with businesses, research institutions and public institutions specializing in industrial and technological development. Moreover Willis had assisted other entrepreneurs in the set-up of biotechnology firms and firms into information technology firms. Willis created his network through his employment in public institutions all of which supported the development and initiation of trade and industry. Over the years Willis had set his marks on the organization and the strategic development in the firm. When the researchers first contacted Willis he arranged a meeting with the ARCH Development Fund, which is the University of Chicago patent office. Based on an evaluation of the technology, ARCH found that there were similar technologies available and that it could not license the technology to an industrial partner. Therefore, the researchers got exclusive rights to commercialize the technology. Afterwards the group returned to Willis and the University Commercialization Centre. The Commercialization Center gave ThermoGen a USD 25,000 loan, which was sufficient to locate the company in the Chicago Technology Parks incubator and to buy some used laboratory equipment. The USD 25,000 loan stretched a long way since none of the involved researchers at that time earned any money from their engagement in ThermoGen. Moreover, this loan was the critical early seed money needed to get the firm started. After getting located, Demirjian again turned to Willis for assistance in making contacts to the industry. The pharmaceutical firms were positive about the prospects of the development of biocatalysts, especially from one of the major companies in the field. Gradually more and more firms contacted ThermoGen asking for information about the services that the company provided. Based on the positive feedback from potential customers, ThermoGen could begin to apply for grants from the SBIR-program to develop the technological platform of the firm.

The interviewees judged the role of the incubator in Chicago Technology as not only economically crucial. The firm definitely would not have existed without the incubator. The access up-to-date laboratory facilities in the initial phase would not have been possible to acquire for the USD 25,000 loan that was the company's seed money. Add to this the different types of consultancy services that the incubator offered or provided for the firm over the years. Surprisingly, the access to these collaborative constellations in the incubator influenced the way

in which ThermoGen structured and organized its activities. The firms inside the incubator for instance developed a flexible collaborative system, a sort of social security system that meant that the firms internally could hire and lend out human resources in periods with ups and downs. In that way a sort of internal fence against bad times was established, this made it possible to preserve jobs for the people that the companies had hired. At the same time this collaborative system meant that all the firms did not necessarily need to acquire all laboratory facilities. For ThermoGen the collaborative system meant that the firm could stay independent of external financial investment for a longer period of time.

#### *AndCare Inc. – Diagnostic Devices*

AndCare was established in 1993 as a merger between two small entrepreneurial firms, LeadCare Inc. and Enzyme Technology Research Group. Steven Wegner, a paediatrician by profession, started LeadCare whereas professor of chemistry Robert Henkens and his late wife Carolyn Henkens founded Enzyme Technology Research Group. The aim of the two companies was very different and so was their point of departure. Wegner's primary interest was in the development of diagnostic devices that could measure the concentration of lead in children's blood. The idea was that the device should be smaller than a paperback book, simple to operate and less expensive (20,000 USD) than the existing test methods. Further the device should display the result of the test immediately after the testing. The idea was that the blood lead test should supplement the existing devices that were the size of a copy machine and varied in price from 50,000-100,000 USD, took skilled personnel to operate and gave the test result after 2-3 days. The basic idea of Enzyme Technology Research Group was to develop into a research boutique that survived from selling projects and doing contract research. AndCare deliberately avoided attracting venture capital firms to the company. The reason for this was that both founders had experienced that venture capital firms took too much ownership, too much control of the technology, and were only interesting in creating quick exits.

Market enactment. In the initial stage, the founders thought that the market for LeadCare® amounted to USD 100 million per year. This calculation was based on President Clinton's declaration of war on blood lead poisoning in 1993, a disease that threatened American children leading to birth defects and lower intelligence levels. At the outset this was an obvious entrepreneurial success that was given attention from powerful public institutions such as the

Federal Centres for Disease Control and Prevention (CDC) and the Federal Food and Drug Administration (FDA).

The basic idea was that AndCare should concentrate on the development of a diagnostic device with very specific functional characteristics, and afterwards search for relevant strategic partners in the areas of production, sales and marketing. It turned out that AndCare, due to the cancellation of the strategic alliances, carried out all the processes by itself. The bottom line is that AndCare developed and had the LeadCare product approved in collaboration with public authorities such as the FDA and the CDC. However, activities such as production and marketing and distribution were outsourced in external networks to a Boston Based company called ESA.

The routines for AndCare were to develop its projects to a certain stage where it was interesting to present the idea to a larger firm with the necessary resources to finish the product in terms of sales and marketing. The search for partnerships consisted of three steps according to Steven Wegner: The first step was to seek for areas where a match could be found between the interests of a partner and the competencies of AndCare. This process was based on existing knowledge of the potential partners, and accessible information from industrial journals, databases and the Internet. Second, before approaching a potential strategic partner the next crucial step was to be aware of what it took for a small research based firm to enter into a strategic partnership with a large corporation. In AndCare's experience, a small firm like AndCare had to be willing to make compromises with its own intentions to establish the partnerships instead of continuing to search for the perfect partnership. Going back to the concept of search and bounded rationality, this illustrates that firms satisfy instead of optimize in the rational sense when it comes to their strategic search processes. Third, the initial contacts had to be established with the right person at the right level of the organization: A person that can take the responsibility and catalyze the organizational decision making process. Initially the contacts are personal based and informal in character. In AndCare's experience, the formalization of the partnership is a long-term process. Being an entrepreneur in the area of biotechnology means that to get access to present your ideas to the right decision makers in large organizations you have to tolerate many rejections, and you only can expect very few positive reactions

There are two ways of analyzing how AndCare tried to create a market for LeadCare®. At the beginning the firm tried to establish its name by letting the researchers

employed at AndCare participate in the scientific community. The researchers filled this role through conference participation and journal publication in acknowledged scientific journals. The prototype testing was done by the use of Steven Wegner's network of paediatricians. AndCare got important information concerning the functional aspects of the prototype not only from the local network in North Carolina, but also from Boston Children's Hospital. To speed up the development process AndCare made an overlap between the network of professional users (paediatricians) and the in-house researchers' scientific networks. This was done by the development of a meeting place, a new network where the researchers and the medical doctors were in direct contact on how to modify the final product.

Relations to university. Three critical incidents meant that AndCare had to reject the first detection system for LeadCare®. First, the detection system was unstable with high temperatures. Second, the system could not fit into the simple-to-use aim that was the initial idea. Third, the market for LeadCare was estimated to be at least USD 100 million per year. But as the problem of lead poisoning diminished, the market decreased to approximately USD 10 million per year. These three incidents led to one of the strategic partners immediately cancelling the strategic alliance. This strategic alliance had been very favourable for AndCare because that particular partner covered all the development expenses in connection to the LeadCare product. Moreover, it had been the agreement that this company would pay for all the costs for having FDA product approval. This was a partnership agreement worth approximately USD 1.5 million. The second company also cancelled their partnership agreement when they had problems keeping track of the original ideas.

Wegner thought that it was important to development a product despite the fact that the earnings from LeadCare® were low or even negative. First, AndCare rejected the first technological concept of the measurement system in order to preserve the functional aims of the LeadCare product. Second, AndCare intensified the development of existing projects. Thereby a search process for alternative ideas was established where AndCare could utilize the measurement system in such way that the development of a new system could be used to diagnostic kit in other diseases or food poisoning was established. The measurement technique that was used was based on research done by a professor at State University of New York, Buffalo (SUNY, Buffalo) that the research director had collaborated with while he was a visiting professor. This concept was applicable and thereafter a prototype was tested in Wegner's

network of paediatricians before the LeadCare product was submitted to the FDA for approval. The mobilization of these networks provided the firm with an extra strategic asset, when the original technological system could not be brought to function in a way that was in accordance the overall goal of the product.

Relations to regulatory bodies and public institutions. AndCare's structuring of partnerships with both private companies and public institutions assisted in the approval of the LeadCare® product by the FDA. First of all, the partnership agreements were formed so that the partner bears the cost of the product approval. Moreover, the partner takes care of the direct contact with the public authorities. However it turned out that AndCare was much more involved than expected. The reason for this was that LeadCare® had attracted great interest from the Federal Centres of Disease Control (CDC) in Atlanta. CDC is responsible for preventing and controlling epidemic diseases throughout the US. CDC had some grants that the firm applied for in the development of LeadCare® and the interest of CDC in the LeadCare product helped to make the FDA aware of the product so that the product was approved for sale more rapidly.

### **Case analysis**

Based on the four case studies, we can address the issue of how and to what extent the firm creation task differ across institutional contexts and what role is played by the network embedded routines in channelling actors' firm creation efforts. An overview of the four cases of firm creation and corresponding answers to the creation of legitimacy in relation to market enactment, university relations, public authorities and venture capitalists are shown in table 2.

Table 2: A cross-case comparison

	<b>Kem-En-Tec</b>	<b>Cobento</b>	<b>ThermoGen</b>	<b>AndCare</b>
<b>Institutional environment</b>	Medical devices	Therapeutics	Platform Technologies	Diagnostics
<b>Market enactment</b>	<p>Created legitimacy through mediating activities such as research publishing, development of a consultancy service oriented towards the major process industries and pharmaceutical firms.</p> <p>Merging two firms from two research institutions to approach a similar market</p>	<p>Legitimacy created by using key actor in hospital sector as bridgehead to other contacts in the international research community</p>	<p>Legitimacy created by developing professional user groups together and formed test groups with future customers.</p> <p>Developed market through long-term relationships with business partners.</p> <p>Extensive use of resource persons network</p>	<p>Used access to Federal Agencies to legitimise product orientation and to search for strategic partners with large pharmaceutical firms.</p> <p>Used one of the founders relations in among local paediatricians area to test and legitimise their product to potential customers/users</p>
<b>Relations to university</b>	<p>Routinized scientific values in the research labs to stay creative</p> <p>Used university labs in the initial stage before moving to incubator</p>	<p>Including key university actors in Company board in order to continue relations with university and maintain access to facilities.</p>	<p>Preserved co-scientific founder active in the board where he served as scientific advisor.</p> <p>Crucial role of incubator also as knowledge provider</p> <p>Used university labs in initial stages.</p>	<p>Extensive use of research director's former research institution, especially in technological problem solving.</p>
<b>Relations to regulatory bodies and public institutions</b>	<p>Did not engage with public programmes and sold projects to industrial partners before engaging with regulatory aspects.</p>	<p>Drawing on contacts to and experience from colleagues at university</p>	<p>Drawing from contacts within the Science parks</p>	<p>Good contacts to regulatory agencies due to the interest in the product from several Federal institutions.</p>
<b>Access to Venture capital</b>	<p>Two Venture capital firms was attracted to the firm and some of the original founders was bought out. VC forced the company to routinize a distinct business model for each of their research projects.</p>	<p>No external routines evoked</p>	<p>No venture capital money. The firm solely relied on public funding from Federal Business Development Programme. No external routines evoked</p>	<p>All Venture Capital was deliberately abandoned. No external routines evoked</p>

In general, the process of evoking external routines in support of firm creation is apparent in all cases studied. Hence, we believe that the case studies lend support to our initial research question and warrant a further investigation of the institutional environment in shaping the entrepreneurs' job. Rather than charting completely unfamiliar territory, the process of founding the company is strongly depending on access to network embedded routines within a particular institutional context. With regard to market enactment, rather than visualizing market potentials based on specific visionary capabilities, biotech entrepreneurs in our cases heavily draw on network-embedded routines for establishing market legitimacy. Perhaps this idea is best illustrated in the AndCare case, where the entrepreneurial idea is to create viable biotech business platforms for other and more resourceful companies to exploit. Moreover, the procedures upon which they draw are not created specifically for the purpose of establishing this particular firm, but are pre-existing routines, available in the institutional context of the entrepreneur. Hence, existing customers, colleagues and links to federal institutions all provide "ready-made" procedures that the biotech entrepreneur can assemble and use for market enactment. Similarly, with respect to contacts to public authorities, the experience from colleagues in similar positions provided a setting of routines available to the entrepreneur in handling legitimacy processes. One issue where routines seemingly fall short in the biotech sector however, concerns access to venture capitalists. It is a consistent impression from our case studies, that there are few if any external routines to draw upon when it comes to creating legitimacy towards venture capitalists. Although biotech entrepreneurs can draw upon specialized and available resources for preparing business plans, it is the cumbersome task of the biotech entrepreneur to initiate and develop contacts with holders of venture capital.

Our second issue concerns the variety of the institutional context and how it affects the network embedded routines available to the entrepreneur. Our expectations were that diversity in institutional contexts would lead to difference either in the constitution of routines and/or in the type of actors holding them. However, the cross-case comparison leaves the strong impression that similarity rather than differences in network embedded routines prevail. The use of personal contacts in the scientific communities for market enactment purposes and the supportive role of host universities seem to be a general characteristic. Moreover, contrary to our expectations there is little difference in the firm creation procedures when comparing the US and Denmark. Seen from an institutional point of view we find this to be a rather interesting observation, since

literature on economic sociology notably that dealing with institutional governance suggest otherwise. For instance, Whitley (1992) talks against universalistic organisational models and in favour of the nation state as a strongly influencing force in the structuring of economic life. However, for several reasons the science-based entrepreneurs in the biotech sector may well be an exception to this principle. First, all of the cases studied here involve entrepreneurs with a scientific background, which more or less all belong to the international scientific community. Within this community there may well be established “industry recipes” concerning how a biotech company should be managed and formed, influencing the norms governing biotech entrepreneurs. Secondly, nearly all potential customers are multinational players therefore the institutional environment of these companies is fairly consistent with regard to legitimacy claims.

### **Concluding discussion**

The aim of our paper has been to initiate a discussion on the role of the biotech entrepreneur versus the institutional context in firm creation processes. So far few efforts have been done in linking the literature on institutional organisation theory with that of firm creation and entrepreneurship. From an institutional point of view, the process of creating legitimacy from external surroundings becomes a key issue in firm creation processes. Our basic idea is that in strongly institutionalized environments such as the biotech sector, external routines supporting entrepreneurs in their firm creation activities prevail and that the role of these routines in forming the entrepreneurial task calls for closer scrutiny. Moreover, we suggested that the character and availability of such routines are dependent on the institutional environment of the organisation. In order to support our claims further, we have conducted an explorative case study, involving four cases from the biotech sector. Although the explorative case study partly supports our initial notion that the definition of the entrepreneurial task largely draws upon the external environment, a more thorough and systematic study of firm creation processes in different institutional contexts is called for.

This discussion points to several possible implications for business people, policy makers and academia. For business people, particularly those considering starting their own business, it seems to be of vital importance to grasp an idea of the challenges related to the creation of

legitimacy and the existing routines embedded in the field for handling these tasks. To the extent that such routines are available, the important issue is to gain access to the networks holding these valuable resources. Such networks are often of an exclusive nature, calling for strong relationship building activities, management of reputation, etc.. Moreover, the extent to which the importance of these networks is acknowledged and is in control of valuable routines, support the idea that the development of entrepreneurial abilities with respect to firm creation hinges on a period of “hanging around”, i.e. building relationships and contacts. Several pieces of anecdotal evidence support this notion.

For policy makers the often rather one-sided focus on solitary entrepreneurs and how to pick these winners and nurture them may need to be replaced with a stronger focus on the importance of solidarity networks and the process of trust-building among entrepreneurs. Skills for business start-ups are available in network contexts and their importance for generating more business start-ups are presently underestimated in most industry policies we know of.

Finally, for academia it is necessary not only to acknowledge that networks are important in processes of firm creation but also to understand what they actually are able to take care of in business creation processes. A stronger focus on the role of the systemic nature of business creation processes is called for, in order to explore the division of labour actually taking place in the micro cosmos of business creation.

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